#### Assessing exposure and health effects for nanomaterial workers: Epidemiologic and biomarker approaches

Paul A. Schulte, Ph.D. Centers for Disease Control and Prevention National Institute for Occupational Safety and Health Cincinnati, OH USA

The findings and conclusions in this report are those of the author and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

Increasing and coalescing evidence from animal studies of some engineered nanomaterials

- Studies of experimental animals show cancer, pulmonary fibrosis, cardiovascular effects
- Consistent patterns of toxic effects related to oxidative stress
- Variability due to contaminants and physicochemical parameters
- Effects seen after relatively short exposure and low doses

## Epidemiologic issues

- Not intrinsically different from studies in other industries
- Inherent characteristics of nanoparticles and contemporary workplaces present difficulty
- Uncertainties in hazards and disease endpoints

#### Heterogeneity of nanoparticles

- Identification of study population
- Temporal factors
- Exposure characterization
- Disease endpoints
- Design and analysis



homogeneous



Heterogeneous concentric



Multifunctional particle



Agglomerate homogeneous



Active particle



Non-spherical heterogeneous



Agglomerate heterogeneous



Non-spherical homogeneous



Fibrous heterogeneous



Fibrous homogeneous



Heterogeneous distributed



Agglomerate fibrous homogeneous



Agglomerate fibrous heterogeneous

Schulte, et al., 2009

- Heterogeneity of nanoparticles
- Identification of study population
- Temporal factors
- Exposure characterization
- Disease endpoints
- Design and analysis



Sector	etc. :: Food			
Sector:	Electronics			
Sector: Me	edicine			
Sector: Ener	rgy			
Sector: Materia	als			
Workplaces	Nanomaterial Type			
	Carbon Nanotubes	Metal Oxides	Dendrimers	Fullerenes Metal Nanomaterials Nanowires Nanostructured Metals Nanoporous Materials Nanoscale Encapsulation
Laboratory Research				
Start up/Pilot				
Manufacturing				
Production				
Disposal				

- Heterogeneity of nanoparticles
- Identification of study population

#### Temporal factors

- Exposure characterization
- Disease endpoints
- Design and analysis

# Dilemmas in identifying workers exposed to engineered nanoparticles





Schulte, 2009

- Heterogeneity of nanoparticles
- Identification of study population
- Temporal factors
- Exposure characterization
- Disease endpoints
- Design and analysis

#### Exposure characterization

- Metrics
- Sufficiency of exposure
- Differential exposure
- Levels by jobs and process

#### Disease endpoints

- Acute
- Chronic
- Distinguish from effects of air pollution and other industrial exposures

#### Design issues

- Sample size
- Retrospective vs. cross-sectional vs. prospective
- Biomarkers

#### Exposure registry

A system for collecting and maintaining in a structured *record,* information on persons with *known or suspected* occupational or environmental exposure to a *hazardous* substance.

## Exposure registry (cont.)

- Used in public health for over 50 years
- May serve as a societal response to hazardous exposures
- May serve as preparatory step for epidemiological studies
- May allow for risk communication

# Questions about exposure registries

- Who would fund/manage them?
- What data would be collected?
- Who would have access to the data?
- Could any investigator with a research proposal have access to the registry?
- Are there non-research implications and responsibilities for those who manage registries?
- Are there expectations for those who participate in them?

#### Model for a Nanomaterials Worker Health Study

